

REMARKS/ARGUMENTS

Reconsideration of this Application and entry of this Amendment are respectfully requested. Claims 1, 3-6, and 8-25 are pending in the present Application. In the Office Action dated May 27, 2010, the Examiner rejected pending claims 1, 3-6, and 8-25 on various grounds. Claims 1 and 6 are amended herein. In view of the amendments and following remarks, favorable consideration and allowance of the Application is respectfully requested.

Claim Objections

Claims 1 and 6 were objected to for informalities, particularly for reciting "the first coating section is disposed on and completely covers the outer surface" and "the second coating section is disposed on and completely covers the outer surface," which is awkward. The Applicant respectfully disagrees.

The Applicant respectfully notes that this nomenclature appeared in the Application as initially filed and claimed, that this nomenclature is well defined in the specification, and that amendment as suggested by the Examiner would make the claims inconsistent with the specification. For example, the stent with an intermittent coating of the present invention provides a coating having a plurality of discrete coating sections disposed on a stent, i.e., an intermittent coating. The individual coating sections can contain different drugs or therapeutic agents, can be made of different polymers, can be made with different solvents, or combinations thereof. The coating sections can be applied in patterns such as ring patterns, striped patterns, spotted patterns, or dot matrix patterns. *See* paragraph [0020]. The stent segments can be provided with one or more discrete coating sections as desired. Stent segment 121 is shown without a coating. Coating section 126 is disposed on stent segment 124, coating sections 128 and 130 are disposed on stent segment 123, and coating sections 132, 134, and 136 are disposed on stent segment 122. *See* Figure 1; paragraph [0023]. *See also* Figures 2-7; Abstract, initial claims 1-4, 6-9, 11, 18; paragraphs [0028]-[0036].

The Applicant respectfully asserts that the meaning of "coating section" is apparent from the specification and drawings submitted at the time the application was filed. In applying the prior art, the claims should be construed to encompass all definitions that are consistent with applicant's use of the term. *See* MPEP 2173.05(a).

Withdrawal of the objection to claims 1 and 6 is respectfully requested.

35 U.S.C. §102 Rejections

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the . . . claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Thus, to warrant the §102 rejection, the references cited by the Examiner must show each and every limitation of the claims in complete detail. The Applicant respectfully asserts that the cited reference fails to do so.

A. Claims 1, 3-6, and 8-10 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Pat. No. 6,616,765 to Castro, et al. (the *Castro* patent).

The Applicant respectfully asserts that the *Castro* patent fails to teach or suggest all the claim limitations.

The *Castro* patent fails to disclose, teach, or suggest:

a stent delivery system including a stent having a plurality of end-to-end cylindrical stent segments, the axes of the plurality of cylindrical stent segments lying along a longitudinal axis of the stent, the stent having a first region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments and a second region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments; and a coating including a first coating section comprising a first polymer and a second coating section comprising a second polymer, the first polymer being different than the second polymer; wherein: the first coating section is a single layer directly adjacent to and completely covering the outer surface in the first region of the longitudinally adjacent cylindrical stent segments; and the second coating section is another single layer directly adjacent to and completely covering the outer surface in the second region of the longitudinally adjacent cylindrical stent segments; and the first region and the second region are discrete, and the first coating section and the second coating section are discrete, as recited in independent claim 1; or

a coated stent including a stent having a plurality of end-to-end cylindrical stent segments, the axes of the plurality of cylindrical stent segments lying along a longitudinal

axis of the stent, the stent having a first region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments and a second region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments; and a coating including a first coating section comprising a first polymer and a second coating section comprising a second polymer, the first polymer being different than the second polymer; wherein: the first coating section is a single layer directly adjacent to and completely covering the outer surface in the first region of the longitudinally adjacent cylindrical stent segments; and the second coating section is another single layer directly adjacent to and completely covering the outer surface in the second region of the longitudinally adjacent cylindrical stent segments; and the first region and the second region are discrete, and the first coating section and the second coating section are discrete, as recited in independent claim 6.

At most, the *Castro* patent discloses a patterned coating on a prosthesis, for example a stent, and a method for forming the coating, plus an apparatus for forming the patterned coating. See Abstract. In another set of embodiments in which second composition 80 is employed, second composition 80 is deposited to at least partially cover first composition 10. In one such embodiment, first composition 10 is deposited on prosthesis 12 as shown in FIG. 14A. Second composition 80 is then deposited to at least partially cover first composition 10 as depicted in FIG. 14B. See Figures 14A, 14B; column 18, lines 33-39. Thus, the *Castro* patent fails to disclose the first coating section being a single layer directly adjacent to and completely covering the outer surface in the first region of the longitudinally adjacent cylindrical stent segments and the second coating section being another single layer directly adjacent to and completely covering the outer surface in the second region of the longitudinally adjacent cylindrical stent segments, as claimed.

Claims 3-5 and claims 8-10 depend directly or indirectly from independent claims 1 and 6, respectively, and so include all the elements and limitations of their respective independent claims. The Applicant therefore submits that the dependent claims are allowable over the *Castro* patent for at least the same reasons as set forth above with respect to their independent claims.

Withdrawal of the rejection of claims 1, 3-6, and 8-10 under 35 U.S.C. §102(e) as being anticipated by the *Castro* patent is respectfully requested.

35 U.S.C. §103 Rejections

Obviousness is a question of law, based on the factual inquiries of 1) determining the scope and content of the prior art; 2) ascertaining the differences between the claimed invention and the prior art; and 3) resolving the level of ordinary skill in the pertinent art. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). See MPEP 2143.03. The Applicant respectfully asserts that the cited reference fails to teach or suggest all the claim limitations.

B. Claims 11-25 were rejected under 35 U.S.C. §103(a) as being unpatentable over the *Castro* patent in view of U.S. Patent No. 5,873,904 to Ragheb, et al. (the *Ragheb* patent).

The Applicant respectfully asserts that the *Castro* patent fails to teach or suggest all the claim limitations.

The *Castro* patent fails to disclose, teach, or suggest:

a method for producing a coated stent including providing a stent having a plurality of end-to-end cylindrical stent segments, the axes of the plurality of cylindrical stent segments lying along a longitudinal axis of the stent, the stent having a first region continuous across at least one pair of longitudinally adjacent cylindrical stent segments and a second region continuous across at least one pair of longitudinally adjacent cylindrical stent segments; mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution; applying the first polymer solution directly to the stent in the first region to form a first coating section of a coating completely covering the outer surface in the first region of the longitudinally adjacent cylindrical stent segments; mixing a second polymer and second therapeutic agent with a second solvent to form a second polymer solution; and applying the second polymer solution directly to the stent in the second region to form a second coating section of the coating completely covering the outer surface in the second region of the longitudinally adjacent cylindrical stent segments, wherein the first coating section and the second coating section are

discrete, and the first region has a longitudinal length greater than the diameter of the stent in an expanded state, as recited in independent claim 11;

a system for producing a coated stent from a stent having a plurality of end-to-end cylindrical stent segments, the axes of the plurality of cylindrical stent segments lying along a longitudinal axis of the stent, the stent having a first region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments and a second region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments, including: means for mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution; means for applying the first polymer solution directly to the stent in the first region to form a first coating section of a coating completely covering the outer surface in the first region of the longitudinally adjacent cylindrical stent segments; means for mixing a second polymer and second therapeutic agent with a second solvent to form a second polymer solution; and means for applying the second polymer solution directly to the stent in the second region to form a second coating section of the coating completely covering the outer surface in the second region of the longitudinally adjacent cylindrical stent segments, wherein the first coating section and the second coating section are discrete, and the first region has a longitudinal length greater than the diameter of the stent in an expanded state, as recited in independent claim 18; or

a coated stent including a stent having a plurality of end-to-end cylindrical stent segments, the axes of the plurality of cylindrical stent segments lying along a longitudinal axis of the stent, the stent having a discrete first region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments and a discrete second region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments; a first polymer including a first therapeutic agent, the first polymer being adjacent to and completely covering the outer surface in the discrete first region of the longitudinally adjacent cylindrical stent segments as a first coating section of a coating; and a second polymer including a second therapeutic agent, the second polymer being adjacent to and completely covering the outer surface in the discrete second region of the longitudinally adjacent cylindrical stent segments as a second coating section of the coating, the first polymer being different than the second polymer, wherein the first

coating section and the second coating section are discrete, and the discrete first region has a longitudinal length greater than the diameter of the stent in an expanded state, as recited in independent claim 22.

At most, the *Castro* patent discloses a patterned coating on a prosthesis, for example a stent, and a method for forming the coating, plus an apparatus for forming the patterned coating. See Abstract. In another set of embodiments in which second composition 80 is employed, second composition 80 is deposited to at least partially cover first composition 10. In one such embodiment, first composition 10 is deposited on prosthesis 12 as shown in FIG. 14A. Second composition 80 is then deposited to at least partially cover first composition 10 as depicted in FIG. 14B. See Figures 14A, 14B; column 18, lines 33-39.

At most, the *Ragheb* patent discloses that the bioactive material may be posited on the one surface of structure 12 in a specific geometric pattern. For example, the tips or arms of a stent may be free of bioactive material, or the bioactive material may be applied in parallel lines, particularly where two or more bioactive materials are applied to the same surface. See column 19, line 64 - column 20, line 3. This is the sole and complete disclosure of the *Ragheb* patent regarding geometric patterns. The *Ragheb* patent also fails to define or describe what the tips or arms of a stent are. Thus, the *Ragheb* patent fails to disclose the first polymer being directly adjacent to and completely covering the outer surface in the discrete first region of the longitudinally adjacent cylindrical stent segments as a first coating section of a coating, and the second polymer being directly adjacent to and completely covering the outer surface in the discrete second region of the longitudinally adjacent cylindrical stent segments as a second coating section of the coating as asserted by the Examiner.

Therefore, the *Castro* patent and the *Ragheb* patent fail to disclose: applying the first polymer solution directly to the stent in the first region to form a first coating section of a coating completely covering the outer surface in the first region of the longitudinally adjacent cylindrical stent segments, and applying the second polymer solution directly to the stent in the second region to form a second coating section of the coating completely covering the outer surface in the second region of the longitudinally adjacent cylindrical stent segments; means for applying the first polymer solution directly to the stent in the first region to form a first coating section of a coating completely covering the outer surface in the first region of the longitudinally adjacent cylindrical stent segments, and means for applying the second polymer

solution directly to the stent in the second region to form a second coating section of the coating completely covering the outer surface in the second region of the longitudinally adjacent cylindrical stent segments; or the first polymer being adjacent to and completely covering the outer surface in the discrete first region of the longitudinally adjacent cylindrical stent segments as a first coating section of a coating, the second polymer being adjacent to and completely covering the outer surface in the discrete second region of the longitudinally adjacent cylindrical stent segments as a second coating section of the coating, as claimed.

Claims 12-17; claims 19-21; and claims 23-25 depend directly or indirectly from independent claims 11, 18, and 22, respectively, and so include all the elements and limitations of their respective independent claims. The Applicant therefore submits that the dependent claims are allowable over the *Castro* patent and the *Ragheb* patent for at least the same reasons as set forth above with respect to their independent claims.

Withdrawal of the rejection of claims 11-25 under 35 U.S.C. §103(a) as being unpatentable over the *Castro* patent and the *Ragheb* patent is respectfully requested.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-0221.

Respectfully submitted,

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